

## **ELECTRODE PLACEMENT DETERMINATION FOR SUBCUTANEOUS CARDIAC MONITORING AND THERAPY**

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### **RELATED APPLICATIONS**

This application claims the benefit of Provisional Patent Application Serial No. 60/462,272, filed on April 11, 2003, to which priority is claimed pursuant to 35 U.S.C. §119(e) and which is hereby incorporated herein by reference.

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### **FIELD OF THE INVENTION**

The present invention relates generally to implantable medical devices and, more particularly, to systems and methods for determining locations suitable for implantation of components for subcutaneous monitors and cardioversion/defibrillation devices.

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### **BACKGROUND OF THE INVENTION**

The healthy heart produces regular, synchronized contractions. Rhythmic contractions of the heart are normally controlled by the sinoatrial (SA) node, which are specialized cells located in the upper right atrium. The SA node is the normal pacemaker of the heart, typically initiating 60-100 heartbeats per minute. When the SA node is pacing the heart normally, the heart is said to be in normal sinus rhythm.

If the heart's electrical activity becomes uncoordinated or irregular, the heart is denoted to be arrhythmic. Cardiac arrhythmia impairs cardiac efficiency and may be

a potential life-threatening event. Cardiac arrhythmias have a number of etiological sources, including tissue damage due to myocardial infarction, infection, or degradation of the heart's ability to generate or synchronize the electrical impulses that coordinate contractions.

5           Bradycardia occurs when the heart rhythm is too slow. This condition may be caused, for example, by impaired function of the SA node, denoted sick sinus syndrome, or by delayed propagation or blockage of the electrical impulse between the atria and ventricles. Bradycardia produces a heart rate that is too slow to maintain adequate circulation.

10           When the heart rate is too rapid, the condition is denoted tachycardia. Tachycardia may have its origin in either the atria or the ventricles. Tachycardias occurring in the atria of the heart, for example, include atrial fibrillation and atrial flutter. Both conditions are characterized by rapid contractions of the atria. Besides being hemodynamically inefficient, the rapid contractions of the atria may also  
15           adversely affect the ventricular rate.

            Ventricular tachycardia occurs, for example, when electrical activity arises in the ventricular myocardium at a rate more rapid than the normal sinus rhythm. Ventricular tachycardia may quickly degenerate into ventricular fibrillation. Ventricular fibrillation is a condition denoted by extremely rapid, uncoordinated  
20           electrical activity within the ventricular tissue. The rapid and erratic excitation of the ventricular tissue prevents synchronized contractions and impairs the heart's ability to effectively pump blood to the body, which is a fatal condition unless the heart is returned to sinus rhythm within a few minutes.

            Implantable cardiac rhythm management systems have been used as an  
25           effective treatment for patients with serious arrhythmias. These systems typically include one or more leads and circuitry to sense signals from one or more interior and/or exterior surfaces of the heart. Such systems also include circuitry for generating electrical pulses that are applied to cardiac tissue at one or more interior

and/or exterior surfaces of the heart. For example, leads extending into the patient's heart are connected to electrodes that contact the myocardium for sensing the heart's electrical signals and for delivering pulses to the heart in accordance with various therapies for treating the arrhythmias described above.

5           Implantable cardioverter/defibrillators (ICDs) have been used as an effective treatment for patients with serious cardiac arrhythmias. For example, a typical ICD includes one or more endocardial leads to which at least one defibrillation electrode is connected. Such ICDs are capable of delivering high-energy shocks to the heart, interrupting the ventricular tachyarrhythmia or ventricular fibrillation, and allowing the  
10 heart to resume normal sinus rhythm. ICDs may also include pacing functionality.

          Although ICDs are very effective at preventing Sudden Cardiac Death (SCD), most people at risk of SCD are not provided with implantable defibrillators. The primary reasons for this unfortunate reality include the limited number of physicians qualified to perform transvenous lead/electrode implantation, a limited number of  
15 surgical facilities adequately equipped to accommodate such cardiac procedures, and a limited number of the at-risk patient population that may safely undergo the required endocardial or epicardial lead/electrode implant procedure.

## SUMMARY OF THE INVENTION

The present invention is directed to systems and methods for determining proper placement of components of implantable cardiac monitoring and/or cardioversion/defibrillation systems. An electrode placement method in accordance with embodiments of the present invention may involve locating at least two surface electrodes on a thorax of a patient at initial locations. An initial surface pacing level may be determined relative to a pacing limit using at least two of the surface electrodes. One or more surface electrode locations may be selected or rejected based on the initial surface pacing level being within the pacing limit, the selected one or more surface electrode locations corresponding to one or more acceptable subcutaneous electrode locations.

The method may further involve relocating at least one of the surface electrodes on the thorax of the patient to a new location, and determining a new surface pacing level at the new location. One or more surface electrode locations may then be selected or rejected using the new surface pacing level. At least one of the surface electrodes may be relocated on the thorax of the patient until a new surface pacing level falls within the pacing limit.

Selecting or rejecting the one or more surface electrode locations may involve selecting a location suitable for implantation of a subcutaneous cardiac stimulation electrode. The method may then involve implanting one or more of the subcutaneous cardiac stimulation electrodes at the selected locations.

In an automated embodiment of a method in accordance with the present invention, at least two surface electrodes may be located, such as by using an array of surface electrode elements. Electrode locations may be selected or rejected by scanning the array of surface electrode elements for their associated pacing levels, such as by selecting one or more electrode element locations having the lowest pacing levels. The lowest pacing level locations may then correspond to locations

suitable for implantation of a subcutaneous cardiac stimulation electrode and a cardiac stimulation system housing, a subcutaneous electrode array, a unitary subcutaneous defibrillation system, or other suitable implantable cardiac device.

5 The method may further involve implanting the subcutaneous cardiac stimulation electrode and the cardiac stimulation system housing at their respective subcutaneous locations, or contra-indicating the patient for implantation of a subcutaneous cardiac stimulation system based on the initial surface pacing level exceeding the pacing limit. The patient may be rejected for implantation of a subcutaneous cardiac stimulation system based on the initial and new surface  
10 pacing levels respectively exceeding the pacing limit.

The method may further involve placing electrodes by locating a first surface electrode in relation to a superior aspect of the patient's heart, and locating a second surface electrode in relation to an inferior aspect of the patient's heart. One or more surface electrodes may be located substantially parallel to a ventricular free  
15 wall of the patient's heart, and may extend a predetermined distance beyond the apex of the patient's heart. One or more surface electrode locations may be selected as a function of a surface cardiac pacing level, and determine one or more subcutaneous electrode implant locations. The method may further involve implanting one or more subcutaneous cardiac stimulation electrodes at the  
20 determined one or more subcutaneous electrode implant locations. One or more of the electrodes may be provided in or on a can or housing.

Systems in accordance with embodiments of the present invention may include a pulse generator configured to deliver a pacing stimulus at a stimulus level. The systems may also include detection circuitry and at least two surface electrodes  
25 coupled to the pulse generator and to the detection circuitry. The two or more surface electrodes may be configured for positioning on a thorax of a patient relative to a patient's heart. A controller may be coupled to the pulse generator and detection circuitry, the controller determining acceptable subcutaneous electrode

locations based at least in part on detection of capture or non-capture resulting from delivery of the pacing stimulus at the stimulus level.

The controller may determine acceptable subcutaneous electrode locations based at least in part on a pre-established proportionality relationship between the stimulus level of the pacing stimulus and a subcutaneous defibrillation level. The subcutaneous defibrillation level, for example, may be a level of subcutaneous defibrillation energy above which a particular subcutaneous defibrillation device is not suited to deliver, or a level of subcutaneous defibrillation energy below which a particular subcutaneous defibrillation device is suited to deliver.

A recording arrangement may be coupled to the controller and configured to record capture threshold data or non-capture data determined for selected thoracic locations of the surface electrodes. A user interface may be coupled to the controller and configured to present capture threshold data or non-capture data determined for selected thoracic locations of the surface electrodes.

Embodiments of systems in accordance with the present invention may further include a cardioversion/defibrillation device configured for performing induction testing on the patient's heart. The pulse generator may be configured to deliver cardioversion/defibrillation stimulation to the patient's heart after inducing an arrhythmia, and measure and/or record stimulus levels for cardioversion/defibrillation.

Embodiments of the system may include a housing, the surface electrodes supported by or coupled to the housing. The housing may include a handle and be configured for hand-held portability. The pulse generator, controller, and detection circuitry may be provided in the housing, and the two or more surface electrodes coupled to the housing or part of the housing, such as in a rigid or semi-rigid (e.g., shape deformable) support assembly. The housing may further include arrhythmia induction and defibrillation circuitry.

The housing may be coupled to or contain an electrode array structure configured to support two or more surface electrodes in an array arrangement, the electrode array structure configured to be positionable on the patient's thorax. The controller may be configured to coordinate scanning of selected combinations of the surface electrodes or electrode array, and identify surface electrode combinations associated with the lowest pacing levels that effect cardiac capture.

The above summary of the present invention is not intended to describe each embodiment or every implementation of the present invention. Advantages and attainments, together with a more complete understanding of the invention, will become apparent and appreciated by referring to the following detailed description and claims taken in conjunction with the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1A and 1B are views of a transthoracic cardiac sensing and/or stimulation device as implanted in a patient in accordance with an embodiment of the present invention;

Figure 1C is a block diagram showing various components of a transthoracic cardiac sensing and/or stimulation device in accordance with an embodiment of the present invention;

Figure 1D is a block diagram illustrating various processing and detection components of a transthoracic cardiac sensing and/or stimulation device in accordance with an embodiment of the present invention;

Figures 2A-2C are diagrams illustrating various components of a transthoracic cardiac sensing and/or stimulation device located in accordance with embodiments of the invention;

Figures 3A-3C are diagrams illustrating electrode subsystem placement relative to a heart in accordance with embodiments of the invention;

Figure 3D illustrates electrode placement and an electrode testing system in accordance with an embodiment of the present invention;

Figure 4A is a graph of proportionality relationships between surface pacing and subcutaneous defibrillation stimulus levels;

Figure 4B is a flow-chart of a method for performing patient stratification in accordance with the present invention;

Figure 4C is a flow-chart of another method for performing patient stratification in accordance with an embodiment of the present invention; and

Figures 5A and 5B are side and bottom views respectively of a hand-held device in accordance with an embodiment of the present invention.

While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will



be described in detail below. It is to be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the invention is intended to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

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## DETAILED DESCRIPTION OF VARIOUS EMBODIMENTS

In the following description of the illustrated embodiments, references are made to the accompanying drawings that form a part hereof, and in which is shown by way of illustration, various embodiments in which the invention may be practiced. It is to be understood that other embodiments may be utilized, and structural and functional changes may be made without departing from the scope of the present invention.

System and methods of the present invention may include one or more of the features, structures, methods, or combinations thereof described hereinbelow. For example, patient stratification and/or electrode positioning systems and methods in accordance with the present invention may be implemented to include one or more of the advantageous features and/or processes described below. It is intended that such devices and methods need not include all of the features described herein, but may be implemented to include selected features that provide for unique structures and/or functionality. Such devices and methods may be implemented to provide a variety of therapeutic and/or diagnostic functions.

Embodiments of the present invention are directed to systems and methods for determining if a patient is a candidate for an implantable cardiac monitoring/stimulation device, such as a subcutaneous defibrillation device.

Embodiments of the present invention are also directed to systems and methods for determining suitable electrode placement locations to improve the performance of the implantable system. One such implantable device, termed an implantable transthoracic cardiac sensing and/or stimulation (ITCS) device, is described herein to include various advantageous features and/or processes. It is understood that the description of features and processes within the context of an ITCS device is provided for non-limiting illustrative purposes only. For example, various features

and processes described herein may be implemented for patient stratification and electrode placement optimization for devices such as cardiac monitors, diagnostic devices, pacemakers, cardioverters/defibrillators, resynchronizers, and the like, including those devices disclosed in the various patents incorporated herein by  
5 reference.

In general terms, an ITCS device may be implanted under the skin in the chest region of a patient. The ITCS device may, for example, be implanted subcutaneously such that all or selected elements of the device are located on the patient's front, back, side, or other body locations suitable for sensing cardiac activity  
10 and delivering cardiac stimulation therapy. It is understood that elements of the ITCS device may be located at several different body locations, such as in the chest, abdominal, or subclavian region with electrode elements respectively located at different regions near, around, in, or on the heart. Examples of electrode configurations, elements of which may be located in accordance with the present  
15 invention, are disclosed in commonly owned US Patent Application No. 10/465,520, filed June 19, 2003, which is hereby incorporated herein by reference in its entirety.

In one configuration, the primary housing (e.g., the active or non-active can) of the ITCS device, for example, may be configured for positioning outside of the rib cage at an intercostal or subcostal location, within the abdomen, or in the upper  
20 chest region (e.g., subclavian location, such as above the third rib). In one implementation, one or more electrodes may be located on the primary housing and/or at other locations about, but not in direct contact with the heart, great vessel or coronary vasculature. In another implementation, one or more electrodes may be located in direct contact with the heart, great vessel or coronary vasculature, such as  
25 via one or more leads. In another implementation, for example, one or more subcutaneous electrode subsystems or electrode arrays may be used to sense cardiac activity and deliver cardiac stimulation energy in an ITCS device

configuration employing an active can or a configuration employing a non-active can. Electrodes may be situated at anterior and/or posterior locations relative to the heart.

Certain configurations illustrated herein are generally described as capable of implementing various functions traditionally performed by an implantable

5 cardioverter/defibrillator (ICD), and may operate in numerous cardioversion/defibrillation modes as are known in the art. Examples of ICD circuitry, structures and functionality, elements of which may be incorporated in an ITCS device of a type contemplated herein, are disclosed in commonly owned U.S. Patent Nos. 5,133,353; 5,179,945; 5,314,459; 5,318,597; 5,620,466; and 5,662,688, which  
10 are hereby incorporated herein by reference in their respective entireties.

In particular configurations, systems and methods may perform functions traditionally performed by pacemakers, such as providing various pacing therapies as are known in the art, in addition to cardioversion/defibrillation therapies.

Examples of pacemaker circuitry, structures and functionality, elements of which may  
15 be incorporated in an ITCS device of a type contemplated herein, are disclosed in commonly owned U.S. Patent Nos. 4,562,841; 5,284,136; 5,376,106; 5,036,849; 5,540,727; 5,836,987; 6,044,298; and 6,055,454, which are hereby incorporated herein by reference in their respective entireties. It is understood that ITCS device configurations may provide for non-physiologic pacing support in addition to, or to the  
20 exclusion of, bradycardia and/or anti-tachycardia pacing therapies.

An ITCS device may implement functionality traditionally provided by cardiac diagnostic devices or cardiac monitors as are known in the art, alternatively or additionally to providing cardioversion/defibrillation therapies. Examples of cardiac monitoring circuitry, structures and functionality, elements of which may be  
25 incorporated in an ITCS device of a type contemplated herein, are disclosed in commonly owned U.S. Patent Nos. 5,313,953; 5,388,578; and 5,411,031, which are hereby incorporated herein by reference in their respective entireties.

An ITCS device may implement various anti-tachyarrhythmia therapies, such as tiered therapies. Subcutaneous, cutaneous, and/or external sensors may be employed to acquire physiologic and non-physiologic information for purposes of enhancing tachyarrhythmia detection and termination. It is understood that configurations, features, and combination of features described in the present disclosure may be implemented in a wide range of implantable medical devices, and that such embodiments and features are not limited to the particular devices described herein.

An ITCS device may be used to implement various diagnostic functions, which may involve performing rate-based, pattern and rate-based, and/or morphological tachyarrhythmia discrimination analyses. Subcutaneous, cutaneous, and/or external sensors may be employed to acquire physiologic and non-physiologic information for purposes of enhancing tachyarrhythmia detection and termination. It is understood that configurations, features, and combination of features described in the present disclosure may be implemented in a wide range of implantable medical devices, and that such embodiments and features are not limited to the particular devices described herein.

Referring now to Figures 1A and 1B of the drawings, there is shown a configuration of an ITCS device implanted in the chest region of a patient at different locations. In the particular configuration shown in Figures 1A and 1B, the ITCS device includes a housing 102 within which various cardiac sensing, detection, processing, and energy delivery circuitry may be housed. It is understood that the components and functionality depicted in the figures and described herein may be implemented in hardware, software, or a combination of hardware and software. It is further understood that the components and functionality depicted as separate or discrete blocks/elements in the figures may be implemented in combination with other components and functionality, and that the depiction of such components and

functionality in individual or integral form is for purposes of clarity of explanation, and not of limitation.

Communications circuitry is disposed within the housing 102 for facilitating communication between the ITCS device and an external communication device, such as a portable or bed-side communication station, patient-carried/worn communication station, or external programmer, for example. The communications circuitry may also facilitate unidirectional or bidirectional communication with one or more external, cutaneous, or subcutaneous physiologic or non-physiologic sensors. The housing 102 is typically configured to include one or more electrodes (e.g., can electrode and/or indifferent electrode). Although the housing 102 is typically configured as an active can, it is appreciated that a non-active can configuration may be implemented, in which case at least two electrodes spaced apart from the housing 102 are employed.

In the configuration shown in Figures 1A and 1B, a subcutaneous electrode 104 may be positioned under the skin in the chest region and situated distal from the housing 102. The subcutaneous and, if applicable, housing electrode(s) may be located about the heart at various locations and orientations, such as at various anterior and/or posterior locations relative to the heart. The subcutaneous electrode 104 is electrically coupled to circuitry within the housing 102 via a lead assembly 106. One or more conductors (e.g., coils or cables) are provided within the lead assembly 106 and electrically couple the subcutaneous electrode 104 with circuitry in the housing 102. One or more sense, sense/pace or defibrillation electrodes may be situated on the elongated structure of the electrode support, the housing 102, and/or the distal electrode assembly (shown as subcutaneous electrode 104 in the configuration shown in Figures 1A and 1B).

In accordance with a further configuration, the lead assembly 106 includes an electrode support assembly, such as a rigid or semi-rigid elongated structure that positionally stabilizes the subcutaneous electrode 104 with respect to the housing

102. In this configuration, the rigidity of the elongated structure maintains a desired spacing between the subcutaneous electrode 104 and the housing 102, and a desired orientation of the subcutaneous electrode 104/housing 102 relative to the patient's heart. The elongated structure may be formed from a structural plastic,  
5 composite or metallic material, and includes, or is covered by, a biocompatible material. Appropriate electrical isolation between the housing 102 and subcutaneous electrode 104 is provided in cases where the elongated structure is formed from an electrically conductive material, such as metal.

In one configuration, the electrode support assembly and the housing 102  
10 define a unitary structure (i.e., a single housing/unit). The electronic components and electrode conductors/connectors are disposed within or on the unitary ITCS device housing/electrode support assembly. At least two electrodes are supported on the unitary structure near opposing ends of the housing/electrode support assembly. The unitary structure may have an arcuate or angled shape, for example.

15 According to another configuration, the electrode support assembly defines a physically separable unit relative to the housing 102. The electrode support assembly includes mechanical and electrical couplings that facilitate mating engagement with corresponding mechanical and electrical couplings of the housing 102. For example, a header block arrangement may be configured to include both  
20 electrical and mechanical couplings that provide for mechanical and electrical connections between the electrode support assembly and housing 102. The header block arrangement may be provided on the housing 102 or the electrode support assembly. Alternatively, a mechanical/electrical coupler may be used to establish mechanical and electrical connections between the electrode support assembly and  
25 housing 102. In such a configuration, a variety of different electrode support assemblies of varying shapes, sizes, and electrode configurations may be made available for physically and electrically connecting to a standard ITCS device housing 102.

An ITCS device may incorporate circuitry, structures and functionality of the subcutaneous implantable medical devices disclosed in commonly owned U.S. Patent Nos. 5,203,348; 5,230,337; 5,360,442; 5,366,496; 5,397,342; 5,391,200; 5,545,202; 5,603,732; and 5,916,243, which are hereby incorporated herein by  
5 reference in their respective entireties.

Depending on the configuration of a particular ITCS device, a delivery system can advantageously be used to facilitate proper placement and orientation of the ITCS device housing and subcutaneous electrode(s). According to one configuration of such a delivery system, a long metal rod similar to conventional trocars can be  
10 used to perform small diameter blunt tissue dissection of the subdermal layers. This tool may be pre-formed straight or curved to facilitate placement of the subcutaneous electrode, or it may be flexible enough to allow the physician to shape it appropriately for a given patient. Examples of delivery tools, elements of which can be incorporated into an ITCS device delivery tool, are disclosed in commonly owned  
15 U.S. Patent No. 5,300,106; US Patent Application No.10/625,833, filed July 23, 2003; US Patent Application No. 10/625,826 filed July 23, 2003; and US Patent Application No. 10/653,456 filed September 2, 2003; which are hereby incorporated herein by reference.

Figure 1C is a block diagram depicting various components of an ITCS device  
20 in accordance with one configuration. According to this configuration, the ITCS device incorporates a processor-based control system 205 which includes a micro-processor 206 coupled to appropriate memory (volatile and non-volatile) 209, it being understood that any logic-based control architecture may be used. The control system 205 is coupled to circuitry and components to sense, detect, and analyze  
25 electrical signals produced by the heart and deliver electrical stimulation energy to the heart under predetermined conditions to treat cardiac arrhythmias. In certain configurations, the control system 205 and associated components also provide pacing therapy to the heart. The electrical energy delivered by the ITCS device may



be in the form of low energy pacing pulses or high-energy pulses for cardioversion or defibrillation.

Cardiac signals are sensed using the subcutaneous electrode(s) 214 and the can or indifferent electrode 207 provided on the ITCS device housing. Cardiac signals may also be sensed using only the subcutaneous electrodes 214, such as in a non-active can configuration. As such, unipolar, bipolar, or combined unipolar/bipolar electrode configurations may be employed. The sensed cardiac signals are received by sensing circuitry 204, which includes sense amplification circuitry and may also include filtering circuitry and an analog-to-digital (A/D) converter. The sensed cardiac signals processed by the sensing circuitry 204 may be received by noise reduction circuitry 203, which may further reduce noise for signals used by the detection circuitry 202. Noise reduction circuitry 203 may also be incorporated after detection circuitry 202 in cases where high power or computationally intensive noise reduction algorithms are required.

In the illustrative configuration shown in Figure 1C, the detection circuitry 202 is coupled to, or otherwise incorporates, noise reduction circuitry 203. The noise reduction circuitry 203 operates to improve the signal-to-noise ratio of sensed cardiac signals by removing noise content of the sensed cardiac signals introduced from various sources. Typical types of transthoracic cardiac signal noise includes electrical noise and noise produced from skeletal muscles, for example.

Detection circuitry 202 typically includes a signal processor that coordinates analysis of the sensed cardiac signals and/or other sensor inputs to detect cardiac arrhythmias, such as, in particular, tachyarrhythmia. Rate based and/or morphological discrimination algorithms may be implemented by the signal processor of the detection circuitry 202 to detect and verify the presence and severity of an arrhythmic episode. Examples of arrhythmia detection and discrimination circuitry, structures, and techniques, elements of which may be implemented by an ITCS device of a type contemplated herein, are disclosed in commonly owned U.S. Patent

Nos. 5,301,677 and 6,438,410, which are hereby incorporated herein by reference in their respective entireties.

The detection circuitry 202 communicates cardiac signal information to the control system 205. Memory circuitry 209 of the control system 205 contains  
5 parameters for operating in various sensing, defibrillation, and pacing modes, and stores data indicative of cardiac signals received by the detection circuitry 202. The memory circuitry 209 may also be configured to store historical ECG and therapy data, which may be used for various purposes and transmitted to an external receiving device as needed or desired.

10 In certain configurations, the ITCS device may include diagnostics circuitry 210. The diagnostics circuitry 210 typically receives input signals from the detection circuitry 202 and the sensing circuitry 204. The diagnostics circuitry 210 provides diagnostics data to the control system 205, it being understood that the control system 205 may incorporate all or part of the diagnostics circuitry 210 or its  
15 functionality. The control system 205 may store and use information provided by the diagnostics circuitry 210 for a variety of diagnostics purposes. This diagnostic information may be stored, for example, subsequent to a triggering event or at predetermined intervals, and may include system diagnostics, such as power source status, therapy delivery history, and/or patient diagnostics. The diagnostic  
20 information may take the form of electrical signals or other sensor data acquired immediately prior to therapy delivery.

According to a configuration that provides cardioversion and defibrillation therapies, the control system 205 processes cardiac signal data received from the detection circuitry 202 and initiates appropriate tachyarrhythmia therapies to  
25 terminate cardiac arrhythmic episodes and return the heart to normal sinus rhythm. The control system 205 is coupled to shock therapy circuitry 216. The shock therapy circuitry 216 is coupled to the subcutaneous electrode(s) 214 and the can or indifferent electrode 207 of the ITCS device housing. Upon command, the shock

therapy circuitry 216 delivers cardioversion and defibrillation stimulation energy to the heart in accordance with a selected cardioversion or defibrillation therapy. In a less sophisticated configuration, the shock therapy circuitry 216 is controlled to deliver defibrillation therapies, in contrast to a configuration that provides for delivery of both cardioversion and defibrillation therapies. Examples of ICD high energy delivery circuitry, structures and functionality, elements of which may be incorporated in an ITCS device of a type contemplated herein, are disclosed in commonly owned U.S. Patent Nos. 5,372,606; 5,411,525; 5,468,254; and 5,634,938, which are hereby incorporated herein by reference in their respective entireties.

In accordance with another configuration, an ITCS device may incorporate a cardiac pacing capability in addition to cardioversion and/or defibrillation capabilities. As is shown in dotted lines in Figure 1C, the ITCS device may include pacing therapy circuitry 230, which is coupled to the control system 205 and the subcutaneous and can/indifferent electrodes 214, 207. Upon command, the pacing therapy circuitry delivers pacing pulses to the heart in accordance with a selected pacing therapy. Control signals, developed in accordance with a pacing regimen by pacemaker circuitry within the control system 205, are initiated and transmitted to the pacing therapy circuitry 230 where pacing pulses are generated. A pacing regimen may be modified by the control system 205.

A number of cardiac pacing therapies are described herein, which are particularly useful in a transthoracic cardiac stimulation device. Such cardiac pacing therapies may be delivered via the pacing therapy circuitry 230 as shown in Figure 1C. Alternatively, cardiac pacing therapies may be delivered via the shock therapy circuitry 216, which effectively obviates the need for separate pacemaker circuitry.

The ITCS device shown in Figure 1C may be configured to receive signals from one or more physiologic and/or non-physiologic sensors 212. Depending on the type of sensor employed, signals generated by the sensors 212 may be communicated to transducer circuitry coupled directly to the detection circuitry or

indirectly via the sensing circuitry. It is noted that certain sensors 212 may transmit sense data to the control system 205 without processing by the detection circuitry 202.

Communications circuitry 218 is coupled to the microprocessor 206 of the control system 205. The communications circuitry 218 allows the ITCS device to communicate with one or more receiving devices or systems situated external to the ITCS device. By way of example, the ITCS device may communicate with a patient-worn, portable or bedside communication system via the communications circuitry 218. In one configuration, one or more physiologic or non-physiologic sensors (subcutaneous, cutaneous, or external of patient) may be equipped with a short-range wireless communication interface, such as an interface conforming to a known communications standard, such as Bluetooth or IEEE 802 standards. Data acquired by such sensors may be communicated to the ITCS device via the communications circuitry 218. It is noted that physiologic or non-physiologic sensors equipped with wireless transmitters or transceivers may communicate with a receiving system external of the patient.

The communications circuitry 218 may allow the ITCS device to communicate with an external programmer. In one configuration, the communications circuitry 218 and the programmer unit (not shown) use a wire loop antenna and a radio frequency telemetric link, as is known in the art, to receive and transmit signals and data between the programmer unit and communications circuitry 218. In this manner, programming commands and data are transferred between the ITCS device and the programmer unit during and after implant. Using a programmer, a physician is able to set or modify various parameters used by the ITCS device. For example, a physician may set or modify parameters affecting sensing, detection, pacing, and defibrillation functions of the ITCS device, including pacing and cardioversion/defibrillation therapy modes.

Typically, the ITCS device is encased and hermetically sealed in a housing suitable for implanting in a human body as is known in the art. Power to the ITCS device is supplied by an electrochemical power source 220 housed within the ITCS device. In one configuration, the power source 220 includes a rechargeable battery. According to this configuration, charging circuitry is coupled to the power source 220 to facilitate repeated non-invasive charging of the power source 220. The communications circuitry 218, or separate receiver circuitry, is configured to receive RF energy transmitted by an external RF energy transmitter. The ITCS device may, in addition to a rechargeable power source, include a non-rechargeable battery. It is understood that a rechargeable power source need not be used, in which case a long-life non-rechargeable battery is employed.

Figure 1D illustrates a configuration of detection circuitry 302 of an ITCS device that includes one or both of rate detection circuitry 310 and morphological analysis circuitry 312. Detection and verification of arrhythmias may be accomplished using rate-based discrimination algorithms as known in the art implemented by the rate detection circuitry 310. Arrhythmic episodes may also be detected and verified by morphology-based analysis of sensed cardiac signals as is known in the art. Tiered or parallel arrhythmia discrimination algorithms may also be implemented using both rate-based and morphologic-based approaches. Further, a rate and pattern-based arrhythmia detection and discrimination approach may be employed to detect and/or verify arrhythmic episodes, such as the approach disclosed in U.S. Patent Nos. 6,487,443; 6,259,947; 6,141,581; 5,855,593; and 5,545,186, which are hereby incorporated herein by reference in their respective entireties.

An ITCS device may be implemented to include a subcutaneous electrode system that provides for cardiac sensing and arrhythmia therapy. According to this approach, an ITCS device may be implemented as a chronically implantable system that performs monitoring, diagnostic and/or therapeutic functions. The ITCS device

may automatically detect and treat cardiac arrhythmias. In one configuration, the ITCS device includes a pulse generator and one or more electrodes that are implanted subcutaneously in the chest region of the body, such as in the anterior thoracic region of the body. The ITCS device may be used to provide atrial and ventricular therapy for bradycardia and tachycardia arrhythmias. Tachyarrhythmia therapy may include cardioversion, defibrillation and anti-tachycardia pacing (ATP), for example, to treat atrial or ventricular tachycardia or fibrillation. Bradycardia therapy may include temporary post-shock pacing for bradycardia or asystole. Methods and systems for implementing post-shock pacing for bradycardia or asystole are described in commonly owned U.S. Patent Application entitled "Subcutaneous Cardiac Stimulator Employing Post-Shock Transthoracic Asystole Prevention Pacing, Serial Number 10/377,274, filed on February 28, 2003, which is incorporated herein by reference in its entirety.

An ITCS device of a type described herein may be used within the structure of an advanced patient management (APM) system. Advanced patient management systems may allow physicians to remotely and automatically monitor cardiac and respiratory functions, as well as other patient conditions. In one example, implantable cardiac rhythm management systems, such as cardiac pacemakers, defibrillators, and resynchronization devices, may be equipped with various telecommunications and information technologies that enable real-time data collection, diagnosis, and treatment of the patient. Various embodiments described herein may be used in connection with advanced patient management. Methods, structures, and/or techniques described herein, which may be adapted to provide for remote patient/device monitoring, diagnosis, therapy, or other APM related methodologies, may incorporate features of one or more of the following references: US Patent Nos. 6,221,011; 6,270,457; 6,277,072; 6,280,380; 6,312,378; 6,336,903; 6,358,203; 6,368,284; 6,398,728; and 6,440,066, which are hereby incorporated herein by reference.

In one configuration, illustrated in Figure 2A, electrode subsystems of the ITCS system include a first electrode subsystem, comprising a can electrode 502, and a second electrode subsystem 504 that may include at least one coil electrode, for example. The second electrode subsystem 504 may include a number of  
5 electrodes used for sensing and/or electrical stimulation. In various configurations, the second electrode subsystem 504 may include a single electrode or a combination of electrodes. The single electrode or combination of electrodes comprising the second electrode subsystem 504 may include coil electrodes, tip electrodes, ring electrodes, multi-element coils, spiral coils, spiral coils mounted on  
10 non-conductive backing, and screen patch electrodes, for example. A suitable non-conductive backing material is silicone rubber, for example.

The can electrode 502 is located on the housing 501 that encloses the ITCS device electronics. In one embodiment, the can electrode 502 includes the entirety of the external surface of housing 501. In other embodiments, various portions of  
15 the housing 501 may be electrically isolated from the can electrode 502 or from tissue. For example, the active area of the can electrode 502 may include all or a portion of either the anterior or posterior surface of the housing 501 to direct current flow in a manner advantageous for cardiac sensing and/or stimulation.

The housing 501 may resemble that of a conventional implantable ICD, is  
20 approximately 20-100 cc in volume, with a thickness of 0.4 to 2 cm and with a surface area on each face of approximately 30 to 100 cm<sup>2</sup>. As previously discussed, portions of the housing may be electrically isolated from tissue to optimally direct current flow. For example, portions of the housing 501 may be covered with a non-conductive, or otherwise electrically resistive, material to direct current flow. Suitable  
25 non-conductive material coatings include those formed from silicone rubber, polyurethane, or parylene, for example.

Figure 2A illustrates the housing 501 and can electrode 502 placed subcutaneously, superior to the heart 510 in the left pectoral region, which is a

location commonly used for conventional pacemaker and defibrillator implants. The second electrode subsystem 504 may include a coil electrode mounted on the distal end of a lead body 506, where the coil is approximately 3-15 French in diameter and 5-12 cm in length. The coil electrode may have a slight preformed curve along its length. The lead may be introduced through the lumen of a subcutaneous sheath, through a common tunneling implant technique, and the second electrode subsystem 504, e.g., comprising a coil electrode, may be placed subcutaneously, deep to any subcutaneous fat and adjacent to the underlying muscle layer.

In this configuration, the second electrode subsystem 504 is located approximately parallel with the inferior aspect of the right ventricle of the heart 510, just inferior to the right ventricular free wall, with one end extending just past the apex of the heart 510. For example, the tip of the electrode subsystem 504 may extend less than about 3 cm and may be about 1-2 cm left lateral to the apex of the heart 510. This electrode arrangement may be used to include a majority of ventricular tissue within a volume defined between the housing 501 and the second electrode subsystem 504. In one configuration, a majority of the ventricular tissue is included within a volume associated with an area bounded by lines drawn between the distal and proximal ends of the second electrode subsystem 504 and the medial and lateral edges of the left pectoral can electrode 502.

In one example arrangement, the volume including a majority of ventricular tissue may be associated with a cross sectional area bounded by lines drawn between the ends of the electrode subsystems 502, 504 or between active elements of the electrode subsystems 502, 504. In one implementation, the lines drawn between active elements of the electrode subsystems 502, 504 may include a medial edge and a lateral edge of the can electrode 502, and a proximal end and a distal end of a coil electrode utilized within the second electrode subsystem 504. Arranging the electrode subsystems so that a majority of ventricular tissue is contained within a volume defined between the active elements of the electrode



subsystems 502, 504 provides an efficient position for defibrillation by increasing the voltage gradient in the ventricles of the heart 510 for a given applied voltage between electrode subsystems 502, 504.

5 In a similar configuration, and as shown in Figure 2B, the housing 501 comprising the can electrode 502 is placed in the right pectoral region. The second electrode subsystem 504 is located more laterally, to again include a majority of the ventricular tissue in a volume defined between the can electrode 502 and the second electrode subsystem 504.

10 In a further configuration, and as shown in Figure 2C, the ITCS device housing 501 containing the electronics (i.e., the can) is not used as an electrode. In this case, an electrode system comprising two electrode subsystems 508, 509 coupled to the housing 501 may be implanted subcutaneously in the chest region of the body, such as in the anterior thorax. The first and the second electrode subsystems 508, 509 are placed in opposition with respect to the ventricles of the heart 510, with the majority of the ventricular tissue of the heart 510 included within a volume defined between the electrode subsystems 508, 509. As illustrated in Figure 2C, the first electrode system 508 is located superior to the heart 510 relative to a superior aspect of the heart 510, e.g., parallel to the left ventricular free wall. The second electrode system 509 is located inferior to the heart 510 and positioned in relation to an inferior aspect of the heart 510, e.g., parallel to the right ventricular free wall.

20 In this configuration, the first and the second electrode subsystems 508, 509 may include any combination of electrodes, including or excluding the can electrode, used for sensing and/or electrical stimulation. In various configurations, the electrode subsystems 508, 509 may each be a single electrode or a combination of electrodes. The electrode or electrodes comprising the first and second electrode subsystems 508, 509 may include any combination of one or more coil electrodes,

tip electrodes, ring electrodes, multi-element coils, spiral coils, spiral coils mounted on non-conductive backing, and screen patch electrodes, for example.

Figures 3A-3C provide additional detailed views of subcutaneous electrode subsystem placement considered particularly useful in patient implant stratification in accordance with embodiments of the present invention. Figure 3A illustrates first and second electrode subsystems configured as a can electrode 602 and a coil electrode 604, respectively. Figure 3A illustrates the can electrode 602 located superior to the heart 610 in the left pectoral region and the coil electrode 604 located inferior to the heart 610, parallel to the right ventricular free wall of the heart 610.

The can electrode 602 and the coil electrode 604 are located so that the majority of ventricular tissue is included within a volume defined between the can electrode 602 and the coil electrode 604. Figure 3A illustrates a cross sectional area 605 formed by the lines drawn between active elements of the can electrode 602 and the coil electrode 604. Lines drawn between active areas of the electrodes 602, 604, may be defined by a medial edge and a lateral edge of the can electrode 602, and a proximal end and a distal end of a coil electrode utilized as the second electrode subsystem 604. The coil electrode 604 extends a predetermined distance beyond the apex of the heart 610, e.g. less than about 3 cm.

A similar configuration is illustrated in Figure 3B. In this embodiment, the can electrode 602 is placed superior to the heart 610 in the right pectoral region. The coil electrode 604 is located inferior to the heart. In one arrangement, the coil electrode is located relative to an inferior aspect of the heart 610, for example, the apex of the heart. The can electrode 602 and the coil electrode 604 are positioned so that the majority of ventricular tissue is included within a volume defined between the can electrode 602 and the coil electrode 604.

Figure 3B illustrates a cross sectional area 605 formed by the lines drawn between active elements of the can electrode 602 and the coil electrode 604. Lines

drawn between active areas of the electrodes 602, 604, may be defined by a medial edge and a lateral edge of the can electrode 602, and a proximal end and a distal end of a coil electrode utilized as the second electrode subsystem 604. The coil electrode 604 extends a predetermined distance beyond the apex of the heart 610, e.g. less than about 3 cm.

Figure 3C illustrates a configuration wherein the pulse generator housing 601 does not include an electrode. In this implementation two electrode subsystems are positioned about the heart so that a majority of ventricular tissue is included within a volume defined between the electrode subsystems. According to this embodiment, the first and second electrodes are configured as first and second coil electrodes 608, 609. The first coil electrode 608 is located superior to the heart 610 and may be located relative to a superior aspect of the heart, e.g., the left ventricular free wall. The second coil electrode 609 is located inferior to the heart 610. The second electrode 609 may be located in relation to an inferior aspect of the heart 610. In one configuration, the second electrode 609 is positioned parallel to the right ventricular free wall with a tip of the electrode 609 extending less than about 3 cm beyond the apex of the heart 610. As illustrated in Figure 3C, the volume defined between the electrodes may be defined by the cross sectional area 605 bounded by lines drawn between active areas of the electrodes 608, 609.

As described above, many variations in device and system configuration are possible that are beneficial to the patient. Anatomical variations and other factors affect the capabilities and efficacy of implantable cardiac monitoring and stimulation systems. Embodiments of the present invention are directed to systems and methods for evaluating and verifying that the systems described above or other implantable systems are capable of operating as intended in a particular patient. Embodiments of the present invention are also directed to systems and methods for determining proper placement of components of these implantable systems. Embodiments of the present invention are further directed to systems and methods

for determining stimulus levels useful for individual patient stratification, and stimulus levels that provide efficacy of subcutaneous defibrillation devices implantable within a given patient.

Using, for example, a subcutaneous defibrillator having components such as those illustrated in Figures 2A and 2B, embodiments of the present invention will be described with reference to Figures 3D and 4A-4C. It should be understood that use of a subcutaneous defibrillator is by way of example only, and that the present invention may be implemented in or with other systems and/or devices disclosed herein either directly or by reference.

Referring now to Figure 3D, many potential locations 800 for locating various subcutaneous defibrillator components are illustrated. Depending on the particular system intended for the patient, and the anatomical variation of the patient, proper locations should be identified for purposes of improving or optimizing component placement. For example, consider an individual patient identified as a potential candidate for implantation of a system as described with reference to Figures 2A and 2B. Referring to Figures 2A-2B and Figure 3D, locations 811 through 819 depict possible right-pectoral locations for placement of the active can 501 of the implantable subcutaneous defibrillator. Locations 801 through 808 depict possible left-pectoral locations for placement of the active can 501 of the implantable subcutaneous defibrillator. Locations 821 through 829 depict possible locations for the coil 504 of the implantable subcutaneous defibrillator.

Defibrillation thresholds typically vary from patient to patient, with some thresholds being beyond the capabilities of some defibrillators. Since surgery is required for implantation of subcutaneous defibrillation devices such as described herein, it is desirable to avoid subjecting patients to an implantation procedure if they are not good candidates for a given system.

The inventors have discovered that, since subcutaneous defibrillation electrodes are generally located away from the heart relative to transvenous defibrillation electrodes, for example, there is a proportionality relationship between surface pacing levels and subcutaneous defibrillation levels that can be advantageously exploited for a number of purposes. This proportionality relationship has been found to be valid when electrodes of a subcutaneous defibrillation device are located relative to the heart within a predefined region of the patient's thorax.

Embodiments of the present invention exploit this relationship for verifying that the implantable systems operate as intended in a particular patient, making that patient a candidate for implantation of the particular defibrillation system.

Embodiments of the present invention also use this proportionality relationship for determining proper placement of components of a given implantable defibrillation system. Embodiments of the present invention further use this proportionality relationship for determining stimulus levels useful for individual patient stratification.

In other embodiments of the present invention, this proportionality relationship is useful for stratifying patients. Examples of patient stratification include determining that a patient is not a candidate for implantation of a 40-Joule defibrillator, but is a candidate for implantation of an 80-Joule defibrillator, or determining that a smaller implantable device is suitable for a patient, thereby saving that patient from the increased bulk of a larger system. It is understood that these examples are for illustration only, and not limitation.

Due to the relationship between subcutaneous defibrillation levels and surface pacing levels, regions of anatomy may be defined for placement of implantable system components. Still referring to Figure 3D, a region 830, a region 840, and a region 841 may be defined wherein the relationship between a surface pacing level necessary to capture the heart of a patient is proportional to the subcutaneous defibrillation level necessary to defibrillate the heart during an arrhythmic episode.

Within the region 830, it would be desirable to provide an indication of a particular location associated with the lowest surface pacing level that captures the patient's heart, which would correspond to a desirable subcutaneous implant location for the active can in Figure 2A. In general, the location of the lowest surface pacing level that effects capture within the region 830 corresponds to the position where the lowest subcutaneous defibrillation threshold level may be realized. Similarly, a region 835 in the right pectoral region may be defined with the regions 840, 841 for a two element subcutaneous defibrillation system, or any of the regions 830, 835, and 840, 841 may be defined for a three or more element subcutaneous defibrillation system.

With sufficient clinical data, the proportionality relationship between surface pacing level and subcutaneous defibrillation level may be sufficiently established for a given subcutaneous defibrillation device to exclude patients from candidacy for a given system based solely on surface pacing/capture determinations. Further, patients may be distinguished as candidates for a defibrillator without subjecting the patient to defibrillation testing. Eliminating defibrillation testing (subjecting a patient to additional arrhythmia episodes and defibrillation shocks) reduces the discomfort and risk associated with defibrillation system implant procedures. However, if defibrillation tests are required, the use of the surface electrodes allows the patient not to be subjected to surgery before he/she is determined to be a candidate for the subcutaneous defibrillation system.

Still referring to Figure 3D, an embodiment of the present invention is illustrated where a patient stratification and electrode location selection process in accordance with embodiments of the present invention are automated. According to one embodiment, an automated system includes a pulse generator 850 connected by a cable 860 to a number of electrodes 800. The pulse generator 850 may also be connected either directly or wirelessly to a user interface 855. The electrodes 800 are shown to include a grouping of the electrodes 811 through 819 within the region

835, a grouping of the electrodes 801 through 808 within the region 830, and a grouping of the electrodes 821 through 829 within the regions 840 and 841.

The electrodes 800 may be individually placed and relocated, or may be provided in one or more groups attached to a substrate such as an adhesive backed polymeric sheet. The electrodes may be large electrodes, such as having an active surface area of about 32 cm<sup>2</sup>, or may include one or more smaller electrodes, such as standard surface EKG electrodes, that may be used individually or in combination. For example, an array of standard EKG surface electrodes may be used, and adjacent pairs or combinations of electrodes may be used simultaneously for pacing and/or defibrillation.

The pulse generator 850 may be used to facilitate selection of appropriate subcutaneous implant locations by scanning through select individual or groups of surface electrodes. For example, the pulse generator 850 may select two electrodes, electrode 807 and 825, as potential locations. The pulse generator 850 may then send a pacing stimulus at a first surface pacing level using the electrodes 807 and electrode 825. The pacing stimulus may be monophasic, biphasic, or multiphasic (e.g., triphasic). The pulse generator 850 may then detect any cardiac response to the first pacing stimulus, such as capture or non-capture. In another embodiment, capture may be detected using another external device, such as a blood sensor (e.g., pulse oximeter), to mitigate noise such as skeletal muscle artifacts. The pulse generator 850 may systematically scan through several groups of electrodes until appropriate subcutaneous implant locations are determined. Systems and methods for capture detection, threshold sensing, and pulse generation are known in the art, and more fully described in the references previously incorporated by reference.

Referring to Figure 4A, a graph illustrates a proportionality relationship between surface pacing level and subcutaneous defibrillation level. Illustrated in Figure 4A is a surface pacing level 748 corresponding, through a proportionality

transfer function, to a defibrillation level 749. Likewise, a surface pacing level 751 corresponds, through the proportionality transfer function, to a subcutaneous defibrillation level 752 and a surface pacing level 753 corresponds, through the proportionality transfer function, to a subcutaneous defibrillation level 754.

5        A surface pacing acceptance level 746 is shown, below which a subcutaneous defibrillation device may be established as acceptable for implantation in a patient if the patient's capture threshold falls at or below the acceptance level 746. An upper limit 747 may be established for a given subcutaneous defibrillation device, above which the subcutaneous defibrillation device has insufficient energy to provide  
10        defibrillation to a patient, either to defibrillate the heart or to ensure a sufficient lifetime of the subcutaneous defibrillation device.

      If a patient's capture threshold associated with surface pacing exceeds the predetermined upper limit 756, the patient would be contra-indicated for implantation of a given implantable subcutaneous defibrillation device. A patient having the  
15        surface pacing level 751 may be above the acceptance level 746 for automatic acceptance, and below the predetermined upper limit 756 for patient contra-indication. Patients in this category may require further testing, such as using defibrillation testing, as will be further described below.

      Referring now to Figure 4B, a patient selection and/or stratification method  
20        700 is illustrated. The patient selection and/or stratification method 700 begins with surface electrode placement 710 or selection (e.g., within an array of electrodes). The electrodes located during surface electrode placement 710 are then used for pacing by delivering a surface pacing pulse 705, and capture/non-capture is sensed to determine if capture may be achieved below an upper surface pacing level 715,  
25        such as a predetermined upper level. The predetermined upper level may be, for example, the level above which the associated defibrillation energy level is beyond the capability of the defibrillator.



A determination 740 is made until acceptable electrode positions are located that provide pacing levels for capture below the upper surface pacing level 715. If no electrode positions can be found below the upper surface pacing level 715, then it is determined 735 that the patient is not a candidate for the subcutaneous defibrillation device. If acceptable electrode positions are located that provide pacing levels below the upper surface pacing level 715, then the patient may be subjected to a defibrillation test 720 to verify that the defibrillation device properly terminates the induced tachyarrhythmia at those electrode positions. The defibrillation test 720 may use a surface defibrillation shock that may be monophasic, biphasic, or multiphasic (e.g., triphasic), and have a desired tilt.

If the determination at block 725 shows that the defibrillation test 720 was not successful, then it is determined 735 that the patient is not a candidate for the subcutaneous defibrillation device, and an intervention may be performed if necessary, such as performing a higher amplitude defibrillation shock, altering the polarity and/or otherwise altering the defibrillation waveform. If the determination at block 725 shows that the defibrillation test 720 was successful, then the patient is determined to be a candidate 745 for the subcutaneous defibrillation device. The patient selection and/or stratification method 700 is illustrative of a process that may be implemented using an automated (fully automatic or semi-automatic) electrode scanning system, or may be performed by a clinician using repositionable surface electrodes.

It is also contemplated by the inventors that an automated stratification system may be built into an implantable ITCS device, to further stratify patients during the continued lifetime of the implant. For example, patient stratification may be an automated process post-implant, or performed routinely at patient follow-ups. This periodic stratification may identify patients who may need to have a device upgrade because of, for example, increased body weight, progression of heart disease, or other pathological or physiological conditions. As described earlier,

results of such routine stratifications may be communicated via an advanced patient management system. Implantable systems that detect capture and that may be useful with embodiments of the present invention that perform routine patient stratification are further described in US Patent Nos. 5,683,431; and 5,331,966, hereby incorporated herein by reference.

As described earlier, sufficient clinical data may eliminate the need for defibrillation testing altogether. The method illustrated in Figure 4C shows a simplified method 750 where the proportionality between the surface pacing levels and implant levels are known. The patient selection and/or stratification method 750 begins with a surface electrode placement 755 (or selection among a group or array of electrodes, as described earlier). The electrodes at the surface electrode placement 755 are then used for pacing by delivering a surface pacing pulse 758, and capture/non-capture is sensed to determine if capture may be achieved below a surface pacing level 760, such as a predetermined acceptance level. The predetermined acceptance level may be, for example, the level below which the associated defibrillation energy level of the subcutaneous defibrillation device is established as acceptable and the proportionality relationship between the surface parameters and the implant parameters is valid.

A determination at block 770 is made until acceptable surface electrode positions are located that provide pacing levels that effect capture below the surface pacing level 760. If no electrode positions can be found that provide pacing levels that effect capture below the surface pacing level 760, then the patient is determined to not be an automatic candidate 775 for the subcutaneous defibrillation device. The patient may then undergo the patient selection and/or stratification method 700 of Figure 4B, or test for an alternate implantable subcutaneous defibrillation system. If acceptable surface electrode positions are located that provide pacing levels that effect capture below the surface pacing level 760, then the patient is a candidate 765 for the subcutaneous defibrillation device.

In another embodiment of the present invention, the electrodes may be affixed to an electrode support assembly, and have a predefined positional relationship relative to one another. A patient screening method using this type of electrode arrangement may involve the steps of providing at least two surface electrodes  
5 connected together and having a fixed spatial relationship. The electrodes may then be located on a thorax of a patient, such as having a first electrode near the apex of the patient's heart, and having a second electrode at a left pectoral region of the patient's thorax.

A surface pacing threshold may be determined for effecting cardiac capture  
10 using the surface electrodes. The patient may be selected or rejected as a candidate for implantation of a subcutaneous defibrillation system based on the surface pacing threshold. If the current positioning is not acceptable, the electrode support assembly may be rotated about the first electrode, for example, by maintaining the first electrode at the heart's apex, but rotating the second electrode  
15 to another location. For example, the second electrode may be rotated from the left pectoral region of the patient's thorax to a right pectoral location of the patient's thorax in search of a more optimum pacing and/or defibrillation threshold. The first electrode may be repositioned as well, if desired.

The electrode support assembly maintains the predefined positional  
20 relationship of the electrodes as they are positioned and rotated on the patient's thorax. The electrode support assembly may be constructed to be substantially rigid or somewhat flexible. The electrode assembly may have an elastic, spring, or mechanical memory that retains a desired configuration after being shaped or manipulated by a clinician. For example, the electrode support assembly can  
25 incorporate a gooseneck or braid system that can be distorted under manual force to take on a desired shape. In this manner, the electrode support assembly can be shape-fit to accommodate the unique anatomical configuration of a given patient, and generally retains a customized shape during the clinical procedure. Shaping of

the electrode support assembly according to this configuration can occur prior to, and during, the clinical procedure, if desired.

Referring now to Figures 5A and 5B, there is illustrated a device 99 that may be used to determine suitable electrode locations in accordance with an embodiment of the present invention. In the particular embodiment shown in Figures 5A and 5B, the device 99 is configured as a hand-held device. The device 99 may be configured for stand-alone operation or cooperative use with another processing device (e.g., a display, recording, and/or pulse generator device). A suitable device useful for pacing and defibrillation and modifiable in accordance with embodiments of the present invention is a Philips HeartStart device available from Philips Medical Systems, 3000 Minuteman Road, Andover, MA 01810-1099.

Figure 5A illustrates a side view of the device 99. The device 99 may include a handle 55, a body 60, a user interface 70, and one or more electrodes 75, 80, 85, and 90. The handle 55 may be grasped by a clinician, and the body 60 may be placed over the thorax of a patient. The device 99 may then perform one or more of the methodologies described above to stratify the patient for purposes of implanting a subcutaneous defibrillation device and/or to assist the clinician in determining suitable or optimal subcutaneous electrode implant locations.

Referring to Figure 5B, a bottom view of the body 60 is illustrated. The body 60 of the device 99 is shown to include a number of electrode locations 22. The electrode locations 22 may be receptacles for connecting electrodes onto the body 60, or may be an array of attached electrodes, such as the electrodes 75, 80, 85, and 90 illustrated in Figure 5A. The number and positions of electrode locations 22 are shown for illustrative purposes only, and the number, size, and positions of the electrodes or electrode receptacles may vary from those shown in Figures 5A and 5B. Moreover, the electrode locations 22 may be stationary, or may be movable to provide the clinician enhanced selectivity with regard to the positions of the electrode locations 22.

Various modifications and additions can be made to the preferred embodiments discussed hereinabove without departing from the scope of the present invention.

Accordingly, the scope of the present invention should not be limited by the particular embodiments described above, but should be defined only by the claims set forth

5 below and equivalents thereof.